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8 **UNITED STATES DISTRICT COURT**  
9 **CENTRAL DISTRICT OF CALIFORNIA**

10 REBECCA WATSON,

11 Plaintiff,

12 vs.

13 KONINKLIJKE PHILIPS N.V.;  
14 PHILIPS NORTH AMERICA LLC; and  
PHILIPS RS NORTH AMERICA LLC,

15 Defendants.

16 Case No.: 5:21-cv-1650

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18 **COMPLAINT FOR MONEY  
DAMAGES  
DEMAND FOR JURY TRIAL**

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- 1. Negligence
- 2. Product Liability: Design Defect
- 3. Product Liability: Manufacturing Defect
- 4. Product Liability: Failure to Warn
- 5. Breach of Express Warranty
- 6. Breach of Implied Warranty Of Merchantability
- 7. Fraudulent Misrepresentation
- 8. Fraud by Omission
- 9. Negligent Misrepresentation

29 Plaintiff REBECCA WATSON (“Plaintiff”), for her complaint against Defendants  
30 Koninklijke Philips N.V. (“Royal Philips”), Philips North America LLC (“Philips NA”),  
31 and Philips RS North America LLC (“Philips RS”) (collectively, Royal Philips, Philips  
32 NA, and Philips RS are “Philips” or the “Defendants”), alleges the following based on (a)  
33 personal knowledge, (b) the investigation of counsel, and (c) information and belief, as  
34 follows:

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36 **I INTRODUCTION**

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38 1. Plaintiff brings this action for injuries caused from the use of Continuous

1 Positive Airway Pressure (CPAP) and Bi-Level Positive Airway Pressure (Bi-Level PAP)  
 2 devices and mechanical ventilators manufactured by Philips, which contain polyester-  
 3 based polyurethane sound abatement foam (“PE-PUR Foam”).

4       2. On April 26, 2021, Philips made a public announcement disclosing it had  
 5 determined there were risks that the PE-PUR Foam used in certain CPAP, Bi-Level PAP,  
 6 and mechanical ventilator devices it manufactured may degrade or off-gas under certain  
 7 circumstances.

8       3. On June 14, 2021, Royal Philips issued a recall in the United States of its  
 9 CPAP, Bi-Level PAP, and mechanical ventilator devices containing PE-PUR Foam,  
 10 because Philips had determined that: (a) the PE-PUR Foam was at risk for degradation  
 11 into particles that may enter the devices’ pathway and be ingested or inhaled by users,  
 12 and (b) the PE-PUR Foam may off-gas certain chemicals during operation. Philips further  
 13 disclosed in its Recall Notice that, “these issues can result in serious injury which can be  
 14 life-threatening, cause permanent impairment, and/or require medical intervention to  
 15 preclude permanent impairment.”

16       4. Philips has disclosed that the absence of visible particles in the devices does  
 17 not mean that PE-PUR Foam breakdown has not already begun. Philips reported that lab  
 18 analysis of the degraded foam reveals the presence of harmful chemicals, including  
 19 Toluene Diamine (“TDA”), Toluene Diisocyanate (“TDI”), and Diethylene Glycol  
 20 (“DEG”).

21       5. Prior to issuing the Recall Notice, Philips received complaints regarding the  
 22 presence of black debris/particles within the airpath circuit of its devices (extending from  
 23 the device outlet, humidifier, tubing, and mask). Philips also received reports of  
 24 headaches, upper airway irritation, cough, chest pressure and sinus infection from users  
 25 of these devices.

26       6. In its Recall Notice, Philips disclosed that the potential risks of particulate  
 27 exposure to users of these devices include irritation (skin, eye, and respiratory tract),  
 28 inflammatory response, headache, asthma, adverse effects to other organs (e.g., kidneys

1 and liver) and toxic carcinogenic effects. The potential risks of chemical exposure due to  
2 off-gassing of PE-PUR Foam in these devices include headache/dizziness, irritation  
3 (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and  
4 carcinogenic effects.

5       7.    Philips recommended that patients using the recalled CPAP and Bi-Level  
6 PAP devices immediately discontinue using their devices and that patients using the  
7 recalled ventilators for life-sustaining therapy consult with their physicians regarding  
8 alternative ventilator options.

9       8.     In or around September 2019, Plaintiff REBECCA WATSON purchased a  
10 Philips DreamStation Auto CPAP device, which she used nightly from the date of  
11 purchase until June 26, 2021.

12       9.     In or around October 2020, Plaintiff began to experience constant sinus  
13 infections, constant coughing, a constant runny nose, bronchitis, and pneumonia which  
14 she never had in the past.

15       10.    In early 2021, Plaintiff developed a dysplasia in her mouth, and underwent  
16 surgery in May 2021 to removal the dysplasia.

17       11. Plaintiff has incurred substantial expenses for medical care and to replace  
18 the device. In addition, Plaintiff experienced various infections including sinus infections,  
19 bronchitis, and pneumonia during use of the Philips' recalled machine. Since being  
20 notified of the recall, Plaintiff has experienced anxiety concerning the serious health risks  
21 she is facing from possible exposure to off-gassed or degraded PE-PUR Foam in the  
22 Recalled machines, including the machine used by Plaintiff.

23       12. Plaintiff seeks to recover damages based on, inter alia, Philips' breach of  
24 express warranty, breach of implied warranties, misrepresentations, omissions, and  
25 breaches of state consumer protection laws in connection with its manufacture, marketing  
26 and sales of devices containing PE-PUR Foam.

## II PARTIES

28 || 13. Plaintiff REBECCA WATSON is a citizen of the State of California.

14. Defendant Royal Philips is a Dutch multinational corporation with its principal place of business located in Amsterdam, Netherlands. Royal Philips is the parent company of the Philips Group of healthcare technology businesses, including Connected Care businesses focusing on Sleep & Respiratory Care. Royal Philips holds directly or indirectly 100% of its subsidiaries Philips NA and Philips RS. Upon information and belief, Royal Philips controls Philips NA and Philips RS in the manufacturing, selling, distributing, and supplying of the recalled CPAP, Bi-Level PAP, and mechanical ventilator devices.

15. Defendant Philips NA is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. Philips NA is a wholly owned subsidiary of Royal Philips.

16. Defendant Philips RS is a Delaware corporation with its principal place of business located at 6501 Living Place, Pittsburgh, Pennsylvania 15206. Philips RS is a wholly owned subsidiary of Royal Philips. Philips RS was formerly operated under the business name Respiromics, Inc. (“Respiromics”). Royal Philips acquired Respiromics in 2008.

### III JURISDICTION AND VENUE

17. Jurisdiction of this Court is based on Diversity of Citizenship and the amount in controversy is well in excess of the jurisdictional limit of \$75,000.00. 28 U.S.C. Section 1332(a)(1).

18. Venue is proper in this judicial District pursuant to 28 U.S.C. § 1391(b) and (c) and 18 U.S.C. § 1965, because Defendants transact business in this District, a substantial part of the events or omissions giving rise to Plaintiff's claims occurred in this District and Plaintiff resides in this District.

19. The Court has personal jurisdiction over Defendants because Defendants conduct substantial business in this District, and the events giving rise to Plaintiff's claims arise out of and relate to Defendants' contacts with this District. Defendants Philips RS and Philips NA are controlled by their parent Royal Philips. Defendants'

1 affiliations with this District are so continuous and systematic as to render them  
 2 essentially at home in the forum State. Further, Defendants have transacted business,  
 3 maintained substantial contacts, purposefully targeted consumers and medical  
 4 professionals for sales of its devices and/or committed overt acts in furtherance of the  
 5 unlawful acts alleged in this Complaint in this District, as well as throughout the United  
 6 States. The unlawful acts of Defendants have been directed at, targeted, and have had the  
 7 effect of causing injury to persons residing in, located in, or doing business in this  
 8 District, as well as throughout the United States.

#### 9                   **IV    FACTUAL BACKGROUND**

##### 10   **A.   Continuous Positive Airway Pressure Therapy**

11       20.   Continuous Positive Airway Pressure (“CPAP”) therapy is a common  
 12 nonsurgical treatment primarily used to treat sleep apnea. CPAP therapy typically  
 13 involves the use of a hose and a nasal or facemask device that delivers constant and  
 14 steady air pressure to an individual’s throat to help individuals breathe.

15       21.   Sleep apnea is a common sleep disorder characterized by repeated  
 16 interruptions in breathing throughout an individual’s sleep cycle. These interruptions,  
 17 called “apneas,” are caused when the soft tissue in an individual’s airway collapses. The  
 18 airway collapse prevents oxygen from reaching the individual’s lungs which can cause a  
 19 buildup of carbon dioxide. If the individual’s brain senses the buildup of carbon dioxide,  
 20 it will briefly rouse the individual from sleep so that the individual’s airway can reopen.  
 21 Often these interruptions are so brief that the individual will not remember. Despite the  
 22 brevity of the interruptions, the sleep cycle disruption caused by sleep apnea can  
 23 dramatically impact a person’s lifestyle, including negatively impacting energy, mental  
 24 performance, and long-term health. CPAP therapy helps treat sleep apnea by preventing  
 25 the person’s airway from collapsing while breathing during sleep cycles, which can help  
 26 prevent interruptions in breathing.

##### 27   **B.   Bi-Level Positive Airway Pressure Therapy**

28       22.   Bi-Level Positive Airway Pressure (“BiPAP”) therapy is a common

1 alternative to CPAP therapy for treating sleep apnea. Similar to CPAP therapy, BiPAP  
 2 therapy is nonsurgical and involves the use of a nasal or facemask device to maintain air  
 3 pressure in an individual's airway. BiPAP therapy is distinguishable from CPAP therapy,  
 4 however, because Bi-Level PAP devices deliver two alternating levels—inspiratory and  
 5 expiratory—of pressurized air into a person's airway, rather than the single continuous  
 6 level of pressurized air delivered by a CPAP device. The inspiratory positive airway  
 7 pressure assists a person as a breath is taken in. Conversely, the expiratory positive  
 8 airway pressure is applied to allow a person to comfortably breathe out. Bi-Level PAP  
 9 devices deliver one level of pressurized air (the inspiratory positive level) to assist as a  
 10 person inhales, and another level (the expiratory level) as a person exhales.

### 11 **C. Mechanical Ventilation**

12 23. Mechanical ventilation is a treatment to help a person breathe when they  
 13 find it difficult or are unable to breathe on their own. A mechanical ventilator pushes  
 14 airflow into the patient's lungs to help them breathe. Mechanical ventilation may be  
 15 invasive ventilation with a tube inserted into the patient's airway, performed in the  
 16 intensive care unit in the hospital or a long-term institutional setting. Non-invasive  
 17 ventilation can be used at home by people with respiratory difficulties.

### 18 **V SUBSTANTIVE ALLEGATIONS**

19 24. Philips developed, marketed, and sold a variety of CPAP and Bi-Level PAP  
 20 respiratory devices and mechanical ventilators under its "Sleep & Respiratory Care"  
 21 segment of its business designed to assist individuals with a number of sleep, breathing,  
 22 and respiratory conditions, including obstructive sleep apnea, central sleep apnea,  
 23 complex sleep apnea syndrome, and Chronic Obstructive Pulmonary Disease (COPD), as  
 24 well as to assist those individuals requiring invasive and non-invasive ventilators for  
 25 acute and sub-acute hospital environments. Philips' CPAP and Bi-Level PAP respirator  
 26 devices and its mechanical ventilators typically cost several hundred, if not thousands of  
 27 dollars. Philips has sold millions of these devices in the United States.

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## A. Philips Sleep & Respiratory Care Devices Endangered Users

25. On April 26, 2021, in its Quarterly Report for Q1 2021, Philips disclosed for the first time, under a section entitled “Regulatory Update,” that device user reports had led to a discovery that the type of PE-PUR Foam Philips used to minimize noise in several CPAP and Bi-Level PAP respirators and mechanical ventilators posed health risks to its users. Specifically, Philips disclosed that “the [PE-PUR] foam may degrade under certain circumstances, influenced by factors including use of unapproved cleaning methods, such as ozone, and certain environmental conditions involving high humidity and temperature.”

26. Seven weeks later, on June 14, 2021, Philips announced a recall of numerous models of CPAP and Bi-Level PAP devices, as well as a variety of its mechanical ventilators “to address identified potential health risks related to the polyester-based polyurethane (PE-PUR) sound abatement foam component in these devices.” Specifically, Philips announced that it had determined that the “PE-PUR foam may degrade into particles which may enter the device’s air pathway and be ingested or inhaled by the user, and the foam may off-gas certain chemicals.” In total, Philips announced that “[b]etween 3 million and 4 million” devices are targeted in the recall.

27. The list of the devices recalled by Philips (the “Recalled Devices” or “Recalled Machines”) include:

## Philips CPAP and Bi-Level PAP Devices

Manufactured Before April 26, 2021 Subject to Recall

### Device Name/Model Type

- E30 (Emergency Use Authorization) – Continuous Ventilator, Minimum Ventilatory Support, Facility Use
- DreamStation ASV; DreamStation ST, AVAPS; SystemOne ASV4; C Series ASV; C Series S/T and AVAPS; OmniLab Advanced Plus – Continuous Ventilator, Non-life Supporting
- SystemOne (Q Series); DreamStation; DreamStation GO; Dorma 400; Dorma

1 500; REMStar SE Auto – Non-continuous Ventilator  
2 Philips Mechanical Respirator Devices  
3 Manufactured Before April 26, 2021 Subject to Recall

4 Device Name/Model Type

5 • Trilogy 100 Ventilator; Trilogy 200 Ventilator; Garbin Plus, Aeris,  
6 LifeVentVentilator – Continuous Ventilator

7 • A-Series BiPAP Hybrid A30; Philips A-Series BiPAP V30 Auto – Continuous  
8 Ventilator, Minimum Ventilatory Support, Facility Use

9 • Philips A-Series BiPAP A40; Philips A-Series BiPAP A30 – Continuous  
10 Ventilator, Non-life Supporting

11 28. According to Philips, the PE-PUR Foam used in Recalled Devices puts users  
12 at risk of suffering from: “[i]rritation (skin, eye, and respiratory tract), inflammatory  
13 response, headache, asthma, adverse effects to other organs (e.g., kidneys and liver) and  
14 toxic carcinogenic affects.”

15 29. Philips reported to physicians that PE-PUR Foam particles “may cause  
16 irritation and airway inflammation, and this may be particularly important for patients  
17 with underlying lung diseases or reduced cardiopulmonary reserve.”

18 30. Further, Philips reported that “based on lab testing and evaluations, it may  
19 be possible that these potential health risks could result in a wide range of potential  
20 patient impact, from transient potential injuries, symptoms and complications, as well as  
21 possibly serious injury which can be life-threatening or cause permanent impairment, or  
22 require medical intervention to preclude permanent impairment.”

23 31. Philips announced that it has received reports of specific complaints from  
24 users of Recalled Devices who suffered from “headache[s], upper airway irritation,  
25 cough, chest pressure and sinus infection.”

26 **B. The Health Risks Associated with Use of the Recalled Devices Renders Them  
27 Worthless**

28 32. As a result of the health risks associated with the use of the Recalled

1 Devices, together with Defendants' concealment of these risks from the date they were  
 2 first reported to Defendants or discovered by Defendants through April 26, 2021, the  
 3 Recalled Devices have been rendered completely worthless or, at the very least, have  
 4 been substantially diminished in value.

5       33. The information described above, including the now-known health risks of  
 6 Philips CPAP devices, Bi-Level PAP devices and mechanical ventilators, the recall, and  
 7 the medical warnings and advice issued by Philips, have rendered the Recalled Devices  
 8 worthless to patients with sleep apnea and respiratory conditions. Individuals not using  
 9 life-supporting ventilators must immediately discontinue their user of the Recalled  
 10 Devices or face serious health risks as grave as organ failure or cancer. If they choose to  
 11 discontinue use of the Recalled Devices they must pay for another expensive device in  
 12 order to receive effective treatment for their sleep apnea and/or respiratory conditions.  
 13 Individuals using life-supporting ventilators must seek an alternative treatment before  
 14 discontinuing use of the Recalled Device.

15       34. Recognizing this, Philips issued the following advice to patients using any of  
 16 the Recalled Devices:

- 17       • “For patients using BiLevel PAP and CPAP devices: Discontinue use of  
 18       affected units and consult with physicians to determine the benefits of  
 19       continuing therapy and potential risks.”
- 20       • “For patients using life-sustaining mechanical ventilator devices: DO NOT  
 21       discontinue or alter prescribed therapy, without consulting physicians to  
 22       determine appropriate next steps.”

23       35. As a result of the above, Plaintiff will have to undertake considerable  
 24 expense replacing the Recalled Device.

25 **C. Philips Unreasonably Delayed its Recall**

26       36. At no time prior to its Regulatory Update on April 26, 2021, did Philips  
 27 disclose to purchasers or users of the Recalled Devices that the PE-PUR Foam contained  
 28 therein may off-gas or degrade upon use. Similarly, prior to the Update, Philips did not

1 disclose any health risks associated with use of the Recalled Devices.

2 37. Defendants have not disclosed when they first discovered or received reports  
3 from users of their Sleep & Respiratory Care devices “regarding the presence of black  
4 debris/particles within the airpath circuit (extending from the device outlet, humidifier,  
5 tubing, and mask).”

6 38. At a minimum, as a result of user reports, Defendants were aware of the off-  
7 gassing and degradation of the PE-PUR Foam used in the Recalled Devices at some point  
8 prior to the recall yet continued to manufacture and sell the Recalled Devices with such  
9 awareness. During this period, Defendants unreasonably and unjustly profited from the  
10 manufacture and sale of the Recalled Devices and unreasonably put users of the Recalled  
11 Devices at risk of development of serious adverse health effects, including organ failure  
12 and cancer.

13 **D. Plaintiff REBECCA WATSON**

14 39. Plaintiff REBECCA WATSON is a resident and citizen of San Bernardino  
15 County, California.

16 40. Plaintiff purchased a Recalled Device, a Philips DreamStation Auto CPAP  
17 device, prior to June 14, 2021.

18 41. The manuals accompanying Plaintiff’s device did not contain any language  
19 or warnings of health risks associated with use of the device, including irritation (skin,  
20 eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to  
21 other organs (e.g., kidneys and liver) and toxic carcinogenic effects. Had Defendants  
22 informed Plaintiff of these risks, she would not have purchased or used the Recalled  
23 Device.

24 42. Without knowing of the health risks associated with use of the Recalled  
25 Device, Plaintiff used the Recalled Device regularly to treat sleep apnea until learning on  
26 June 26, 2021, that the devices were recalled.

27 43. As a result of the health risks associated with continued use of the Recalled  
28 Device, Plaintiff was diagnosed with sinus infections, bronchitis, pneumonia, and

1 dysplasia in her mouth.

2 **VI TOLLING AND ESTOPPEL**

3 **A. DISCOVERY RULE TOLLING**

4 44. Plaintiff had no way of knowing about Philips' conduct with respect to the  
5 health risks associated with the use of the Recalled Device.

6 45. Plaintiff, through the exercise of reasonable care, could not have discovered  
7 the conduct by Philips alleged herein. Further, Plaintiff did not discover and did not know  
8 of facts that would have caused a reasonable person to suspect that Philips was engaged  
9 in the conduct alleged herein.

10 46. For these, reasons, all applicable statutes of limitation have been tolled by  
11 the discovery rule with respect to claims asserted by Plaintiff.

12 **B. FRAUDULENT CONCEALMENT TOLLING**

13 47. By failing to provide immediate notice of the adverse health effects  
14 associated with continued use of the Recalled Device, Philips concealed its conduct and  
15 the existence of the claims asserted herein from Plaintiff.

16 48. Upon information and belief, Philips intended its acts to conceal the facts  
17 and claims from Plaintiff. Plaintiff was unaware of the facts alleged herein without any  
18 fault or lack of diligence on her part and could not have reasonably discovered  
19 Defendants' conduct. For this reason, any statute of limitations that otherwise may apply  
20 to the claims of Plaintiff should be tolled.

21 **VII CLAIMS FOR RELIEF**

22 **FIRST CAUSE OF ACTION**

23 **NEGLIGENCE**

24 49. Defendants had a duty to individuals, including the Plaintiff, to use  
25 reasonable care in designing, manufacturing, marketing, labeling, packaging and selling  
26 the recalled machines, including the Recalled Devices.

27 50. Defendants were negligent in failing to use reasonable care as described  
28 herein in designing and manufacturing, the recalled machines, as well as the machine that

1 Plaintiff purchased and used. Defendants breached their aforementioned duty by:

- 2 a. Failing to design the recalled machines so as to avoid an unreasonable
- 3 and increased risk of harm of cancer and other injuries in users;
- 4 b. Including in the design of the recalled machines flawed polyurethane
- 5 PE-PUR sound abatement foam that could break down, flake off
- 6 and/or chemicalize and infiltrate the device's air pathway while the
- 7 user is sleeping, exposing them to increased and unnecessary risk of
- 8 cancer as well as other injuries;
- 9 c. Manufacturing certain Philips machines, including the recalled
- 10 machines, with a specific lot and/or lots of flawed polyurethane PE-
- 11 PUR sound abatement foam that could break down, flake off and/or
- 12 chemicalize and infiltrate the device's air pathway while the user is
- 13 sleeping, exposing them to increased and unnecessary risk of cancer
- 14 as well as other injuries;
- 15 d. Otherwise negligently or carelessly designing, manufacturing,
- 16 marketing, labeling, packaging and/or selling the Recalled Devices.

17 51. Defendants also negligently failed to warn or instruct the Plaintiff in the  
18 following manners:

- 19 a. the recalled machine's flawed polyurethane PE-PUR sound abatement
- 20 foam propensities to break down, flake off and/or chemicalize and
- 21 infiltrate the device's air pathway while the user is sleeping, exposing
- 22 them to increased and unnecessary risk of cancer as well as other
- 23 injuries;
- 24 b. the recalled machine's polyurethane PE-PUR sound abatement foam
- 25 propensities to degradation, fragmentation and/or chemicalization;
- 26 c. the rate and manner in which the polyurethane PE-PUR sound
- 27 abatement foam would break down, flake off and/or chemicalize and
- 28 infiltrate the device's air pathway while the user is sleeping;

- d. the risk of chronic inflammation resulting from use of the recalled machines;
- e. the risk of chronic infections resulting from the recalled machines;
- f. the risk of lung, kidney, and/or rectal cancers from exposure to the foam;
- g. the need for corrective or revision surgery to adjust or remove cancerous tumors and/or nodules as a result of usage of the recalled machines;
- h. the severity of complications that could arise as a result of implantation of the recalled machines;

52. As a direct and proximate result of Defendants' negligence, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

53. WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

## **SECOND CAUSE OF ACTION**

## PRODUCT LIABILITY: DESIGN DEFECT

54. The recalled machine used by Plaintiff was not reasonably safe for its intended uses and was defective as described herein with respect to its design. As previously stated, the machine's design defects include, but are not limited to:

- a. the use of polyurethane PE-PUR sound abatement foam in the recalled machines and the immune reaction that results from such material, causing adverse reactions and injuries;

- b. Failing to design the recalled machines so as to avoid an unreasonable and increased risk of harm of cancer and other injuries in users;
- c. Including in the design of the recalled machines flawed polyurethane PE-PUR sound abatement foam that could break down, flake off and/or chemicalize and infiltrate the device's air pathway while the user is sleeping, exposing them to increased and unnecessary risk of cancer as well as other injuries;
- d. Failing to use alternatively available sound abatement materials and/or foams in the recalled machines, such as plastic, silicone, or rubber, which would not break down, flake off and/or chemicalize and infiltrate the device's air pathway while the user is sleeping;
- e. Otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging and/or selling the recalled machines.

55. At all times, the use of the recalled machines, as well as Plaintiff's use of the Recalled Device (and its components, such as the facemask) was at all times foreseeable and foreseen by Defendants as it was used by Plaintiff in the manner intended by Defendants.

56. The recalled machine used by Plaintiff, was defective in their design in that it failed to perform as safely as a reasonable consumer would expect when used in an intended or reasonably foreseeable manner.

57. The recalled machines, including the Recalled Device used by Plaintiff, are further defective in that the risks of danger inherent in its design outweigh the benefits, in that the gravity of danger posed by the design was great, the likelihood that such danger would cause injury was substantial, there were feasible, safer alternative designs known to Defendants at the time of manufacture, the financial costs of an improved design was minor and there were likely no adverse consequences to the product, or to the user, that would result from an alternative design.

58. Defendants, and each of them, knew that the recalled machines, including

1 the Plaintiff's Recalled Device, and the component parts of these CPAP/BIPAP machines  
2 would be purchased and used without inspection for defects in the design of the machine  
3 or its masks/attachments.

4       59. The recalled machines, including the Plaintiff's Recalled Device, and the  
5 component parts of these machines were defective when they left the control of each of  
6 these Defendants.

7       60. As a direct and proximate result of the recalled machines, including  
8 Plaintiff's Recalled Device, and the aforementioned defects as described herein, the  
9 Plaintiff has experienced significant mental and physical pain and suffering, has sustained  
10 permanent injury, has undergone medical treatment and will likely undergo future  
11 medical treatment and procedures, has suffered financial or economic loss, including, but  
12 not limited to, obligations for medical services and expenses, lost income, and other  
13 damages.

14 61. Defendants are strictly liable to the Plaintiff for designing, manufacturing,  
15 marketing, labeling, packaging and selling the recalled machines, including Plaintiff's  
16 Recalled Device.

17       62. As a direct and proximate result of one or more of the above-stated negligent  
18 acts, Plaintiff has suffered and will continue to suffer injury of a personal and pecuniary  
19 nature, including pain and suffering, medical expenses, lost income, and disability.

20       63. WHEREFORE, Plaintiff demands judgment against Defendants, and each of  
21 them, individually, jointly, severally and in the alternative, and requests compensatory  
22 damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such  
23 further relief as the Court deems equitable and just.

### **THIRD CAUSE OF ACTION**

## **PRODUCT LIABILITY: MANUFACTURING DEFECT**

64. At all times, the use of the recalled machines, as well as Plaintiff's use of the  
Recalled Device (and its components, such as the facemask) was at all times foreseeable  
and foreseen by Defendants as it was used by Plaintiff in the manner intended by

1 Defendants.

2       65. The recalled machines were defective at the time of their manufacture,  
 3 development, production, testing, inspection, endorsement, sale and distribution, and at  
 4 the time they left the possession of the Defendants, in that, and not by way of limitation,  
 5 the products differed from the Defendants' intended result and intended design and  
 6 specifications, and from other ostensibly identical units of the same product line.

7       66. Defendants, and each of them, knew or should have known of the defective  
 8 nature of the recalled machines, including (among other things), that the PE-PUR foam  
 9 used in the recalled machine's component parts was prone to flaking, chemicalization,  
 10 disintegration, that it could enter the user's airways while they slept, and created an  
 11 unreasonably high risk while in use, and would foreseeably result in injury or death to the  
 12 public, purchasers, and/or consumers.

13       67. The Defendants, and each of them, knew or should have known of the  
 14 defective nature of the recalled machines, and the component parts of these CPAP/BIPAP  
 15 machines, including among other things, that the PE-PUR foam used in the recalled  
 16 machine's component parts was prone to flaking, chemicalization, disintegration, that it  
 17 could enter the user's airways while they slept, and created an unreasonably high risk  
 18 while in use, and would foreseeably result in injury or death to the public, purchasers,  
 19 and/or consumers.

20       68. Specifically, the Defendants improperly designed the recalled machines by  
 21 manufacturing certain Philips machines, including the recalled machines, with a specific  
 22 lot and/or lots of flawed polyurethane PE-PUR sound abatement foam that could break  
 23 down, flake off and/or chemicalize and infiltrate the device's air pathway while the user  
 24 is sleeping, exposing them to increased and unnecessary risk of cancer, including cancer,  
 25 as well as other injuries.

26       69. As a direct and proximate result of one or more of the above-stated negligent  
 27 acts, Plaintiff has suffered and will continue to suffer injury of a personal and pecuniary  
 28 nature, including pain and suffering, medical expenses, lost income, and disability.

70. WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

## **FOURTH CAUSE OF ACTION**

## **PRODUCT LIABILITY: FAILURE TO WARN**

71. The recalled machines, including the Recalled Device used by Plaintiff, were not reasonably safe for their intended uses and were defective as described herein as a matter of law due to its lack of appropriate and necessary warnings. Specifically, Defendants did not provide sufficient or adequate warnings including, but not limited to, the following:

- a. the recalled machine's flawed polyurethane PE-PUR sound abatement foam propensities to break down, flake off and/or chemicalize and infiltrate the device's air pathway while the user is sleeping, exposing them to increased and unnecessary risk of cancer, including cancer, as well as other injuries;
- b. the recalled machine's polyurethane PE-PUR sound abatement foam propensities to degradation, fragmentation and/or chemicalization;
- c. the rate and manner in which the polyurethane PE-PUR sound abatement foam would break down, flake off and/or chemicalize and infiltrate the device's air pathway while the user is sleeping;
- d. the risk of chronic inflammation resulting from use of the recalled machines;
- e. the risk of chronic infections resulting from the recalled machines;
- f. the risk of lung, kidney, and/or rectal cancers from exposure to the foam;
- g. the need for corrective or revision surgery to adjust or remove cancerous tumors and/or nodules as a result of usage of the recalled

machines;

h. the severity of complications that could arise as a result of implantation of the recalled machines;

72. As a direct and proximate result of the recalled machine's aforementioned defects as described herein, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

73. Defendants are strictly liable to the Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective device.

74. WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

## **FIFTH CAUSE OF ACTION**

## **BREACH OF EXPRESS WARRANTY**

75. Philips marketed and sold the Recalled Device into the stream of commerce with the intent that the Recalled Device would be purchased by Plaintiff and other members of the general public.

76. Philips expressly warranted, advertised, and represented to Plaintiff that the Recalled Device was safe and appropriate for human use.

77. Philips made these express warranties regarding the Recalled Device's quality and fitness for use in writing through its website, advertisements, and marketing materials, and on the Recalled Device's packaging and labels. These express warranties became part of the basis of the bargain that Plaintiff entered into upon purchasing the Recalled Device.

78. Philips' advertisements, warranties, representations, and omissions regarding

1 health risks associated with the Recalled Device, were made in connection with the sale  
 2 of the Recalled Device to Plaintiff. Plaintiff relied on Philips' advertisements, warranties,  
 3 representations, and omissions regarding the Recalled Device in deciding whether to  
 4 purchase and use Philips' Recalled Device.

5 79. The recalled machines, including the Recalled Device used by Plaintiff, did  
 6 not conform to Philips' advertisements, warranties, representations, and omissions in that  
 7 they are not safe, healthy, and appropriate for human use, and pose risks of serious injury  
 8 and disease, including organ failure and cancer.

9 80. Philips therefore breached its express warranties by placing the recalled  
 10 machines, including the machine used by Plaintiff, into the stream of commerce and  
 11 selling it to consumers, when their use posed health risks, had dangerous effects and were  
 12 unsafe, rendering these products unfit for their intended use and purpose, and unsafe and  
 13 unsuitable for consumer use as marketed by Philips. These associated health effects  
 14 substantially impair the use, value, and safety of the Recalled machines, and rendered the  
 15 machines worthless.

16 81. Philips was aware, or should have been aware, of the toxic or dangerous  
 17 health effects from the use of the recalled machines, including the machine used by  
 18 Plaintiff, but nowhere on the package labeling or package inserts or on Philips' websites  
 19 or other marketing materials did Philips warn Plaintiff she was at risk of developing  
 20 adverse health effects as a result of the dangerous PE-PUR Foam used in the recalled  
 21 machines

22 82. Instead, Philips concealed the dangerous health effects of the PE-PUR Foam  
 23 used in the recalled machines, including the machine used by Plaintiff and deceptively  
 24 represented that these products were safe, healthy, and appropriate for use. Philips thus  
 25 utterly failed to ensure that the material representations they were making to consumers  
 26 were true.

27 83. The adverse health effects associated with use of the recalled machines,  
 28 including the machine used by Plaintiff existed when they left Philips' possession or

1 control and were sold to Plaintiff. The dangers associated with use of the recalled  
2 machines were undiscoverable by Plaintiff at the time of purchase of the Recalled  
3 Device.

4 84. As manufacturers, marketers, advertisers, distributors and sellers of the  
5 Recalled Devices, Philips had exclusive knowledge and notice of the fact that the  
6 Recalled Devices did not conform to the affirmations of fact and promises.

7 85. In addition, or in the alternative, to the formation of an express contract,  
8 Philips made each of the above-described representations and omissions to induce  
9 Plaintiff to rely on such representations and omissions.

10 86. Philips' affirmations of fact and promises and its omissions were material,  
11 and Plaintiff reasonably relied upon such representations and omissions in purchasing  
12 and using the Recalled Device.

13 87. All conditions precedent to Philips' liability for its breach of express  
14 warranty have been performed by Plaintiff.

15 88. Affording Philips an opportunity to cure its breaches of written warranties  
16 would be unnecessary and futile here. Philips was placed on reasonable notice from user  
17 reports and its lab testing that the PE-PUR Foam in the Recalled Devices, including the  
18 machine used by Plaintiff was unsafe. Philips had ample opportunity either to stop using  
19 the PEPUR Foam or to replace the PE-PUR Foam in the Recalled Devices to make them  
20 safe and healthy for use by Plaintiff but failed to do so until now.

21 89. As a direct and proximate result of the recalled machines, including the  
22 machine's aforementioned defects as described herein, the Plaintiff has experienced  
23 significant mental and physical pain and suffering, has sustained permanent injury, has  
24 undergone medical treatment and will likely undergo further medical treatment and  
25 procedures, has suffered financial or economic loss, including, but not limited to,  
26 obligations for medical services and expenses, and/or lost income, and other damages.

27 90. WHEREFORE, Plaintiff demands judgment against Defendants, and each of  
28 them, individually, jointly, severally and in the alternative, and requests compensatory

1 damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such  
 2 further relief as the Court deems equitable and just.

3 **SIXTH CAUSE OF ACTION**

4 **BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY**

5 91. Philips are merchants engaging in the sale of goods to Plaintiff and members  
 6 of the general public.

7 92. There was a direct sale of goods from Philips to Plaintiff, creating privity  
 8 between Plaintiff and Defendants.

9 93. At all times mentioned herein, Philips manufactured or supplied the recalled  
 10 machines, including the machine used by Plaintiff, and prior to the time of use, Philips  
 11 impliedly warranted to Plaintiff that the Recalled Devices, including the machine used by  
 12 Plaintiff was of merchantable quality, fit for their ordinary use, and conformed to the  
 13 promises and affirmations of fact and omissions made on the labels and packaging,  
 14 including that the machines were safe and appropriate for human use. Plaintiff relied on  
 15 Philips' promises and affirmations of fact and omissions when she purchased and used  
 16 the Recalled Device.

17 94. Contrary to these representations and warranties, the Recalled Devices,  
 18 including the machine used by Plaintiff was not fit for its ordinary use and did not  
 19 conform to Philips' affirmations of fact and promises and omissions because use of the  
 20 Recalled Devices is accompanied by the risk of adverse health effects, which does not  
 21 conform to the labels and packaging of these devices.

22 95. Philips breached its implied warranties by selling a Recalled Device,  
 23 including the machine used by Plaintiff that failed to conform to the promises or  
 24 affirmations of fact made on the packaging or label, as use of each Recalled Device was  
 25 accompanied by the risk of developing adverse health effects that do not conform to the  
 26 packaging or label.

27 96. Philips was on notice of this breach, as it was made aware of the adverse  
 28 health effects accompanying use of the Recalled Devices through user reports submitted

1 to Philips and through lab testing.

2 97. Privity exists because Philips impliedly warranted to Plaintiff through the  
 3 warranting, packaging, advertising, marketing, and labeling that the Recalled Devices  
 4 were natural, and suitable for use to treat health conditions, and made no mention of the  
 5 attendant health risks associated with use of the Recalled Devices.

6 98. As a direct and proximate result of the Recalled Devices, including the  
 7 aforementioned defects as described herein, the Plaintiff has experienced significant  
 8 mental and physical pain and suffering, has sustained permanent injury, has undergone  
 9 medical treatment and will likely undergo further medical treatment and procedures, has  
 10 suffered financial or economic loss, including, but not limited to, obligations for medical  
 11 services and expenses, and/or lost income, and other damages.

12 99. WHEREFORE, Plaintiff demands judgment against Defendants, and each of  
 13 them, individually, jointly, severally and in the alternative, and requests compensatory  
 14 damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such  
 15 further relief as the Court deems equitable and just.

16 **SEVENTH CAUSE OF ACTION**

17 **FRAUDULENT MISREPRESENTATION**

18 100. Philips failed to advise Plaintiff that the Recalled Devices, including the  
 19 machine used by Plaintiff posed serious health risks to their users and Philips falsely  
 20 represented to Plaintiff that the Recalled Devices were safe for human use.

21 101. Philips intentionally, knowingly, and recklessly made these  
 22 misrepresentations and omissions to induce Plaintiff and other members of the general  
 23 public to purchase the Recalled Devices, including the machine used by Plaintiff.

24 102. Philips knew that its representations and omissions about the Recalled  
 25 Devices, including the machine used by Plaintiff, were false in that the Recalled Devices  
 26 contained PE-PUR Foam and thus were at risk of causing adverse health effects to users  
 27 of the Recalled Devices which does not conform to the products' labels, packaging,  
 28 advertising, and statements. Philips knowingly allowed its packaging, labels,

advertisements, promotional materials, and websites to intentionally mislead consumers, such as Plaintiff.

103. Plaintiff did in fact rely on these omissions and misrepresentations and purchased and used a Recalled Device to her detriment. Given the deceptive manner in which Philips advertised, represented, and otherwise promoted the Recalled Devices, Plaintiff's reliance on Philips' omissions and misrepresentations was justifiable.

104. As a direct and proximate result of the recalled machines, including the machine's aforementioned defects as described herein, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

105. WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

## **EIGHTH CAUSE OF ACTION**

## FRAUD BY OMISSION

106. Philips concealed from and failed to disclose to Plaintiff that use of Recalled Devices, including the machine used by Plaintiff is accompanied by a risk of adverse health effects, which does not conform to the products' labels, packaging, advertising, and statements.

107. Philips was under a duty to disclose to Plaintiff the true quality, characteristics, ingredients and suitability of the Recalled Devices, including the machine used by Plaintiff because:

- a. Philips was in a superior position to know the true state of facts about its products;
- b. Philips was in a superior position to know the risks associated with the

- use of, characteristics of, and suitability of the Recalled Devices; and
- c. Philips knew that Plaintiff could not reasonably have been expected to learn or discover prior to purchasing the Recalled Device that there were misrepresentations and omissions by Philips in the packaging, labels, advertising, and websites regarding the health risks associated with use of these devices.

108. The facts concealed or not disclosed by Philips to Plaintiff were material in that a reasonable consumer would have considered them important when deciding whether to purchase the Recalled Device.

109. Plaintiff justifiably relied on Philips' omissions to her detriment. The detriment is evident from the true quality, characteristics, and risk associated with the use of the Recalled Devices, including the machine used by Plaintiff, which is inferior when compared to how the Recalled Devices are advertised and represented by Philips.

110. As a direct and proximate result of the Recalled Devices, including the machine's aforementioned defects as described herein, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

111. WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

**NINTH CAUSE OF ACTION**  
**NEGLIGENT MISREPRESENTATION**

112. Philips had a duty to Plaintiff to exercise reasonable and ordinary care in the developing, testing, manufacture, marketing, distribution, and sale of the Recalled Devices, including the machine used by Plaintiff.

1       113. Philips breached its duty to Plaintiff by developing, testing, manufacturing,  
2 advertising, marketing, distributing, and selling products to Plaintiff that did not have the  
3 qualities, characteristics, and suitability for use as advertised by Philips and by failing to  
4 promptly remove the Recalled Devices, including the machine used by Plaintiff from the  
5 marketplace or to take other appropriate remedial action upon becoming aware of the  
6 health risks of the Recalled Devices.

7       114. Philips knew or should have known that the qualities and characteristics of  
8 the Recalled Devices, including the machine used by Plaintiff were not as advertised or  
9 suitable for their intended use and were otherwise not as warranted and represented by  
10 Philips. Specifically, Philips knew or should have known that:

- 11       a. the use of the Recalled Devices was accompanied by risks of adverse health  
12            effects that do not conform to the packaging and labeling;
- 13       b. the Recalled Devices were adulterated, or at risk of being adulterated, by the  
14            PE-PUR Foam; and
- 15       c. the Recalled Devices were otherwise not as warranted and represented by  
16            Philips.

17       115. As a direct and proximate result of Defendants' negligence, the Plaintiff has  
18 experienced significant mental and physical pain and suffering, has sustained permanent  
19 injury, has undergone medical treatment and will likely undergo further medical  
20 treatment and procedures, has suffered financial or economic loss, including, but not  
21 limited to, obligations for medical services and expenses, lost income, and other  
22 damages.

23       116. WHEREFORE, Plaintiff demands judgment against Defendants, and each of  
24 them, individually, jointly, severally and in the alternative, and requests compensatory  
25 damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such  
26 further relief as the Court deems equitable and just.

27       ///

28       ///

## **VIII PRAYER FOR RELIEF**

WHEREFORE, Plaintiff prays for judgment against the Defendants, and each of them, as follows.

- a. For past and future general damages on each cause of action, according to proof;
- b. For past and future pain and suffering, according to proof;
- c. For past and future hospital, medical, nursing care, treatment and incidental expenses, according to proof;
- d. For past and future loss of earnings and earning power, according to proof;
- e. For past and future mental and emotional distress, according to proof;
- f. For restitution, according to proof;
- g. For punitive damages in an amount appropriate to punish and/or set an example of Defendants, or in any other way appropriate;
- h. For past and future costs of suit incurred herein, and attorney's fees as may be allowed by law; and
- i. For such other and further relief as the Court may deem just and proper.

Date: September 29, 2021

## **MCCUNE·WRIGHT·AREVALO, LLP**

By: /s/ Kristy M. Arevalo  
Kristy M. Arevalo  
Attorney for Plaintiff

## **DEMAND FOR JURY TRIAL**

Plaintiff demands a trial by jury for all issues so triable.

Date: September 29, 2021

## McCUNE·WRIGHT·AREVALO, LLP

By: /s/ Kristy M. Arevalo  
Kristy M. Arevalo  
*Attorney for Plaintiff*